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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

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MARX, I

ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/821,025	Applicant(s) Bijl et al.
	Examiner Irene Marx	Group Art Unit 1651

Responsive to communication(s) filed on May 31, 2000.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 27-31, 33, and 41-53 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 27-31, 33, and 41-53 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The amendment filed 5/31/00 is acknowledged. Claims 27-31, 33 and 41-53 are being examined on the merits. Claims 1-26 and 34-36 are withdrawn from consideration as directed to a non-elected invention.

The numbering of claims is not accordance with 37 C.F.R. § 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 C.F.R. § 1.121(b), they must be renumbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 37-49 have been renumbered 41-53, respectively.

The amendment to the claims should be made in accordance with 37 CFR 1.121(a)(2)(ii) which states:

(ii) Claim cancellation or rewriting: A claim may be amended by directions to cancel the claim or by rewriting such claim with underlining below the matter added and brackets around the matter deleted. The rewriting of a claim in this form will be construed as directing the deletion of the previous version of that claim. If a previously rewritten claim is again rewritten, underlining and bracketing will be applied relative to the previous version of the claim, with the parenthetical expression "twice amended," "three times amended," etc., following the original claim number. The original claim number followed by that parenthetical expression must be used for the rewritten claim. No interlineations or deletions of any prior amendment may appear in the currently submitted version of the claim. A claim canceled by amendment (not deleted and rewritten) can be reinstated only by a subsequent amendment presenting the claim as a new claim with a new claim number.

Claim 30 is improperly amended in that the material added to the claim is not underlined in its entirety. Cf. the last two lines of the claim, for example. Clarification and correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-31, 33 and 41-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for extruded granules consisting essentially of intact dead microorganisms or dead microbial cells or for granular particles consisting essentially of intact dead microbial cells or fungi. As a matter fact, there is an inherent inconsistency between submitting cells to an extrusion and granulation process and designation as "intact".

Regarding basis for dead cells of *Pichia*, at Specification, page 11, line 4, for example, it is noted that *Pichia* cells are specifically excluded from pasteurization.

Therefore, this material raises the issue of new matter and should be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-31, 33 and 41-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague, indefinite and inconsistent in the recitation "granulate formed by extrusion which consists essentially of intact dead microorganisms or dead microbial cells". As a matter fact, there is an inherent inconsistency between killing cells and submitting the killed cells to an extrusion and granulation process and the designation "intact", since the cells are killed and granulated, and cannot properly be deemed to be unaltered.

It remains unclear how it is assured in the extrusion process as claim-designated that the access is necessarily "via **the** pores". Applicants' arguments directed to the extraction process and the size of the pores are noted. However, pore size is not a claim designated limitation. It is further unclear which compounds are intended, except in dependent claims. Moreover, the claims are silent regarding how "compounds" are to be isolated or extracted in this context, particularly since there does not seem to be a clearly defined correlation between the type of microorganism, the nature of the solvent and/or the class of compound to be isolated.

Claim 30 is vague and indefinite in that the phrase "the intact dead cells" fails to find proper antecedent basis within the claim.

Claim 33 remains objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may not depend on another multiple dependent claim. See MPEP § 608.01(n). However, the claim has been treated on the merits to the extent that it is understood. Contrary to applicant's contention, this objection is not obviated and pertains to claim 33 rather than claims 32 and/or 37. Claims 32 and 37 are cancelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27-31, 33, and 41 are/remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Huang *et al.* or Cockram *et al.*

Claims 28-31 and 33 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rhodes *et al.*

In view of the inconsistency regarding whether the cells are killed or intact, the rejection over Rhodes *et al.* is maintained. Moreover, the transitional phrase "consisting essentially of" does not exclude the inclusion of cells that are alive. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551 - 52, 190 USPQ 461, 463 (CCPA 1976)(emphasis in original)(Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well - known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). See also *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama - Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. v. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063 - 64 (Bd. Pat. App. & Inter. 1989)(“Although ‘consisting essentially of’ is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps . . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification . . . [I]t is an applicant’s burden to establish that a step practiced in a prior art method is excluded from his claims by ‘consisting essentially of’ language.”).

Even when reading the claims in light of the specification, there is no indication that particular properties are possessed by compositions of extruded granules consisting essentially of intact dead microorganisms or dead microbial cells or for granular particles consisting essentially of intact dead microbial cells or fungi. It is unclear that such compositions are actually disclosed. For example, the record does not proffer substantiation for a contention that live cells would materially change the characteristics of applicant's invention.

Applicants contend that spores are not the materials from which one readily extracts "commercial" amounts of intracellular compounds such as β -carotene and Vitamin B-12. Yet the claims are drawn to unidentified microorganisms or fungi and includes a structural limitation regarding access to solvent extraction. There is nothing of record to fairly suggest to one of ordinary skill in the art that the claim designated microorganisms, fungi and yeasts necessarily constitute materials from which one readily extracts "commercial" amounts of intracellular compounds such as β -carotene and Vitamin B-12 as implied. In addition, regarding Rhodes *et al.* in particular, one of ordinary skill in the art would have compelling motivation to solvent extract entomopathogenic compounds from the granulated extruded fungal product of Rhodes *et al.*. Therefore this argument is without merit.

Applicants recitation of the structure of granules and pores in the response citing the specification at page 20 et seq. are not claim limitations. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. *In re Van Guens*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In addition, the limitations of the claims must be clear and unambiguous to one of ordinary skill in the art. It is noted that the benefits of a specific granulation process argued at page 6, penultimate paragraph, are disclosed in the specification. With respect to any properties of the specific granulates recited in the specification, the limitations in the specification may not be read into the claims. It is well settled that claims must stand on their own and particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are not deemed to meet these requirements, since the respective process steps and parameters are not claim designated.

Applicants criticize the Cockram *et al.* reference as specifically failing to disclose a "solvent-extracted compound" and the Huang reference for not being akin to the extraction of vitamin B-12 (response, page 8). Yet the claims are drawn to extruded granules of microorganisms or fungi rather than to a solvent-extracted compound or a process for the extraction of vitamin B-12, as noted *supra*.

Regarding the presence of pores in Huang, applicants' attention is directed to col. 4, line 63, wherein pores are specifically disclosed. Contrary to applicants' contentions, the heat killed fungal product is ground in a meat grinder, and then extruded which would reasonably be expected by one or ordinary skill in the art to result in a product which is a porous granulated extrudate. (col. 6, lines 49 et seq.)

Applicants contend that the product of Cockram *et al.* remains fibrous rather than granular. (Response, page 9). However, the reference suggests that an extrudate $\frac{1}{2}$ " square may be dried and cut into chunks. It is submitted that such a product reads on the instant dried granular material and contains pores as evidenced by item 20 in Figure 4 and Col. 3, lines 18-21).

The arguments by counsel to attempt to patentably distinguish the products of the prior art over the instant composition by arguing that the different purposes of the prior art suggest preparation and product differences are not persuasive and have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence.

Therefore the rejection is deemed proper and it is adhered to.

Claims 42-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang *et al.* or Cockram *et al.* or Rhodes *et al.*. and further taken with Akimoto *et al.*.

As noted *supra* in the rejections under 35 U.S.C. §102/103, the references disclose dried extruded porous granular compositions of microorganisms. The references differ from the claimed invention in the nature of the microorganisms involved and in the presence of specific compounds in these microorganisms. However, Akimoto *et al.* adequately demonstrate that *Mortierella* are known to contain polyunsaturated fatty acids such as arachidonic acid which can be extracted with a solvent (See, e.g., Table 1). In addition, the reference discloses that *Aspergillus* is also a suitable source of compounds that can be extracted with a solvent.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the product of each of Huang *et al.* or Cockram *et al.* or Rhodes *et al.* selecting a dried granular product containing a useful chemical, such as *Mortierella* or *Aspergillus* containing polyunsaturated fatty acids, as suggested by the teachings of Akimoto *et al.* for the expected benefits of providing a valuable dried granular product which is stable and easy to handle.

Claims 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang *et al.* or Cockram *et al.* or Rhodes *et al.*. and further taken with Casey *et al.*.

As noted *supra* in the rejections under 35 U.S.C §102/103, the references disclose dried extruded porous granular compositions of microorganisms. The references differ from the claimed invention in the nature of the microorganisms involved and in the presence of specific compounds in these microorganisms. However, Casey *et al.* adequately demonstrate that *Pichia* are known to contain tetraacetylsphingosine (TAPS) which can be extracted with a solvent (See, e.g., page 3, lines 32 et seq.).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the product of each of Huang *et al.* or Cockram *et al.* or Rhodes *et al.* selecting a dried granular product containing a useful chemical, such as *Pichia* containing TAPS, as suggested by Casey *et al.* for the expected benefits of providing a valuable dried granular product which is stable and easy to handle.

Claims 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang *et al.* or Cockram *et al.* or Rhodes *et al.*. and further taken with Rickes.

As noted *supra* in the rejections under 35 U.S.C §102/103, the references disclose dried extruded porous granular compositions of microorganisms. The references differ from the claimed invention in the nature of the microorganisms involved and in the presence of specific compounds in these microorganisms. However, Rickes adequately demonstrate that a variety of bacteria are known to contain vitamin B-12 which can be extracted with a solvent (See, e.g., col. 16).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the product of each of Huang *et al.* or Cockram *et al.* or Rhodes *et al.* selecting a dried granular product containing a useful chemical, such as *Lactobacillus*, *Pseudomonas* or *Streptomyces*, as suggested by Rickes for the expected benefits of providing a valuable dried granular product which is stable and easy to handle.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196 .


Irene Marx
Primary Examiner
Art Unit 1651